REMARKS

In the Office Action dated January 3, 2006, claims 29-38 were examined with the result that all claims were rejected. In response, Applicant has canceled claims 30, 31 and 32 and amended claim 29. In view of the above amendments and following remarks, reconsideration of this application is requested.

Before turning to the rejection of record, Applicant would first like the Examiner to note that the "Cross Reference" section of the application has been updated by inserting the patent number of the parent application. Secondly, Applicant has revised the claims to call for the oral administration of the claimed compound in the only independent claim which is claim 29. This amendment necessitated the cancellation of dependent claims 30, 31 and 32. Applicant believes claim 29, as now amended, is distinguishable over the references cited.

The Double Patenting Rejection

In the Office Action, claims 29-38 were rejected under the judicially created Doctrine of Obviousness Type Double Patenting as being unpatentable over claims 21-35 of U.S. 5,945,410 as well as claims 27-37 of U.S. Patent 6,127,559. The Examiner indicated that although the instant claims are not identical to the claims in the '410 and '559 references, they are not patentably distinct from each other because the presently claimed compounds contain a methyl group at the carbon 2 position of the A-ring whereas the prior art references disclose an alkyl group at the carbon 2 position. Further, the Examiner indicates that because the instant claims and the prior art claims are both drawn to a method of treating metabolic bone diseases, it would have been obvious to one of ordinary skill in the art to prepare additional compounds useful for the treatment of metabolic bone diseases because the references teach the use of 2-alkyl vitamin D compounds for such purposes.

The Examiner indicated that a timely filed Terminal Disclaimer may be used to overcome the obviousness type double patenting rejections made in this Office Action. However, Applicant believes the compound as now claimed in claim 29 may be distinguished based on its biological activities from what is disclosed in the '410 and '559 references. Therefore, Applicant believes the use of the instantly claimed compound to treat metabolic bone disease by orally administering it to a subject is not obvious in view of the prior art disclosure.

As noted above, Applicant has revised claim 29 to call for the oral administration of the claimed compound. The significance of this Amendment is that Applicant has found that the presently claimed compound (which does not have a 25-hydroxyl group) will have significant ability to treat metabolic bone diseases when administered orally, as compared to other 2-alkyl vitamin D compounds that might have a 25-hydroxyl group. It will also be much more effective as an oral treatment than 1α,25-dihydroxyvitamin D_3.

To support Applicant's position, Applicant includes herewith two articles. First is Frolik et al, "The Stimulation of 1,25-Dihydroxycholecalciferol Metabolism in Vitamin D-deficient Rats by 1,25-Dihydroxycholecalciferol Treatment," Journal of Clinical Investigation, Vol. 52, No. 3, pp. 543-548, (March 1973). The second article is Tanaka et al, "Role of 1,25-Dihydroxycholecalciferol in Calcification of Bone and Maintenance of Serum Calcium Concentration in the Rat," Journal of Nutrition, Vol. 102, pp. 1569-1578, (1972). With regard to the Frolik et al article, Applicant refers the Examiner to the first column on page 547, and in particular the last two sentences of the first full paragraph (highlighted in yellow). It states therein that 1α,25-dihydroxyvitamin D_3 is essentially destroyed in the intestine when given orally, which clearly reduces its therapeutic efficacy.

This is confirmed in the Tanaka et al article beginning at the bottom of the right hand column of page 1571 under the "Results" section. In particular, Applicant refers the Examiner to the statements made on pages 1572 and 1573 (highlighted in yellow) which clearly conclude that 1α,25-dihydroxyvitamin D_3 is not effective when administered orally. Thus, it is known in the art that vitamin D compounds such as 1α,25-dihydroxyvitamin D_3 are not effective when administered orally. The 24-hydroxylase enzyme found in the intestines will destroy most of any vitamin D compound administered orally, at least those that contain a 25-hydroxyl group. This is because the 24-hydroxylase enzyme requires the 25-hydroxyl group to become activated. Therefore, vitamin D compounds with the 25-hydroxyl group cannot be administered orally, and be therapeutically effective.

In contrast, Applicant has discovered that the presently claimed compound, i.e. the 20(S)-1α-hydroxy-2α-methyl-19-nor-vitamin D_3 compound survives the 24-hydroxylase enzyme because it does not have a 25-hydroxyl group. Therefore, this compound is much more effective than the compound 2AMD discussed in the prior art '410 and '559 references.

Thus, from what is taught in the '410 and '559 references, one skilled in the art would not recognize that the presently claimed compound would be much more effective as an oral treatment for metabolic bone diseases than the prior art 2-alkyl compounds, especially 2AMD. There is simply nothing taught in the '410 and '559 references regarding this so-called "first pass effect." Thus, Applicant believes claim 29, as amended herein, is patentable over the '410 and '559 references. Therefore, Applicant believes the Examiner should withdraw the obviousness type double patenting rejection based upon what is taught in the '410 and '559 references.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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